

REMARKS

The reminder of this Amendment as set forth under appropriate subheadings for the convenience of the Examiner.

Summary of Interview with Examiner's El-Kaissi and Patel

On Thursday, August 11, 2011, Applicants' attorney, N. Scott Pierce (Reg. No. 34,900), and a named inventor on this application, Prof. Hugh Herr, conducted a telephone interview with Examiners El-Kaissi and Patel regarding the most recent Office Action, issued May 11, 2011. Applicants and Applicants' attorney thank the Examiners for having granted this interview.

During the interview, Examiners El-Kaissi and Patel requested that the claims be amended to include an actuator, a sensor and a computer controller as positive elements of the independent device claims. Applicants have amended the claims to do so and have amended other claims dependent from them to be consistent with the newly-amended independent claims. The independent method claims have also been amended, as appropriate, to reflect the actuator, sensor and controller of the device claims.

Applicants' attorney and Prof. Herr also went through the specification with Examiners El-Kaissi and Patel. Applicants' attorney pointed out how Figs. 6 and 7, and the related text, demonstrate how the claimed invention is an improvement over orthoses that have no, or constant, impedance during a walk cycle.

As also stated during the interview, none of the references relied upon to support rejections for lack of novelty under 35 U.S.C. § 102 or for obviousness under 35 U.S.C. § 103 exhibit modulation of impedance that is updating or adaptive in nature. Support for modulation that is updating or adaptive in nature can be found in the specification at, for example: page 2, line 6; page 7, lines 25-29; page 7, lines 10-12 and 19-20; page 10, lines 29 and 31; page 12, with reference to Figs. 6 and 7; page 13, line 19 through page 14, line 5; and page 16, lines 11-13.

Claim Amendments

The claims have been amended in response to comments made by Examiner El-Kaissi in a rejection of Claims 1-23 and 25-40 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicants regard as the invention. The amendments made to the claims in response to the rejection under 35 U.S.C. § 112 include replacement of the phrase “during each walk cycle” with “from step-to-step of a walk cycle,” for which support can be found in the specification at, for example, page 8, lines 19-28. Support for other amendments to the claims can be found throughout the specification.

The claims have also been amended to positively recite an actuator, a controller and at least one of an ankle angle sensor and a ground reaction force sensor. Support for these amendments to these amendments to the claims can be found in the specification at, for example, page 2, lines 21-26; page 3, lines 4-7; page 4, lines 11-21; page 5, lines 5-23; page 7, lines 8-21; and lines 25-29; and Figs. 1 and 3-7, and associated text.

No new matter has been added.

Rejection of Claims Under 35 U.S.C. §112 Second Paragraph

Claims 1-23 and 25-40 stand rejected under 35 U.S.C. §112 second paragraph as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner stated that various limitations and claims appear to be method steps and suggested amending the language of the claims to positively recite structural elements of the claims by stating that those elements are configured to perform the recited function.

In response to the Examiner’s suggestions, Applicants have amended the claims. Applicants have also replaced the language of “during each walk cycle” with “from step-to-step of a walk cycle,” thereby providing antecedent basis for the term “walk cycle.” Support for this amendment can be found in the application at, for example, page 8, lines 19-28.

With respect to claims 34 and 35, the Examiner stated that it is unclear where “of a torsional spring control” is coming from in claim 34 and it is unclear where “spring damper control” is coming from in claim 35. Claim 34 has been amended to delete the phrase “of a torsional spring control.” Claim 35 does not include the phrase “spring damper control.” Applicants respectfully requests clarification of the Examiner’s rejection of this claim.

Regarding claims 37-41, support for adaptive modulation of joint impedance can be found in the specification at, for example, page 10, line 19 through page 11, line 3, page 12, lines 16-19, page 14, lines 2-5 and page 15, lines 7-11 as stated in an Amendment filed that introduced

claims 37-41 on August 26, 2008. New claims 37-41 were discussed in a telephone interview conducted on November 1, 2007. The relevant portion of the interview summary states:

Still alternatively, it was suggested to amend the independent claims to include a limitation wherein the modulation to the joint impedance is adaptive in nature such that information from each gait cycle causes further modulations that vary the joint impedance response from one gait cycle to the next, which both the Applicant and the Examiner see as a substantive aspect of the novelty of the invention.

The subject matter of new claims 37-41 was not rejected by the Examiner for lack of written description under 35 U.S.C. § 112 in the next Office Action, dated February 25, 2009.

As amended, Applicants believe that the claims comply with the Examiner's suggestions for compliance with 35 U.S.C. § 112 second paragraph and, therefore, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. §102(a), 102(b), 102(e) and 103

In response to the most recent amendment, filed on March 19, 2010, the Examiner suggested that Applicants positively recite "impedance," such as by inserting the language "actively adjusting, varying, or selectively varying, joint impedance," because, according to the Examiner, "the claim does not positively recite modulating any impedance or detecting any impedance in order to change the impedance."

The term "impedance" was removed from the claims on November 9, 2007, in response to the Examiner's interpretation of U.S. 5,112,296 to Beard *et al.*, because the Examiner at the time contended that the term impedance could be interpreted to embrace a resistance of an ankle joint in response to when a foot is lifted by a cable, whereby an ankle joint moves from no resistance to full resistance when the foot is lifted by the cable. Applicants stated at the time that Beard *et al.* do not disclose or suggest modulating stiffness or damping of the ankle joint during walking. However, in order to clarify the meaning of the claim, the word "impedance" was replaced with the phrase "modulating joint stiffness or damping during walking."

In order to further clarify the claims, and in response to the Examiner's statement that "impedance" is not recited in the claim, Applicants are now amending the claims to specify that

the device is configured to modulate, by computer controlled actuation of impedance, including a joint stiffness or damping of an ankle joint. Therefore, “joint stiffness or damping of an ankle joint” are identified as types of impedance that are modulated by Applicants’ claimed variable-impedance active ankle foot orthosis.

Impedance, in its most general form, is the stiffness, damping and mass of a system. To control impedance of a joint, its stiffness, damping and/or inertial properties are controlled and modulated. Changing the position of an orthotic joint does not, in and of itself, modulate impedance. Conversely, modulation of impedance does not require any change in the position of a joint. Simply locking, unlocking, engaging or disengaging a physical spring is not modulation of impedance in a continuous updating manner. Two related articles directed to impedance are attached as Exhibits A and B, and are included in a Supplemental Information Disclosure Statement filed with this Amendment. In Exhibit A, at pages 305-306, and in Exhibit B, at pages 8 and 9, the authors discuss impedance control as controlling stiffness (the relationship between force and position), damping (the relationship between force and velocity) and inertia.

Rejection of Claims 37 and 39 Under 35 U.S.C. § 102(b) in View of Beard ‘296

Claims 37 and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Beard et al. (U.S. Patent 5,112,296, hereinafter Beard ‘296). Specifically, the Examiner stated that, with respect to Claim 37, Beard ‘296 discloses a variable-impedance active foot orthosis for modulating a joint stiffness or damping of an ankle joint at least three times during each walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises foot drop. With respect to Claim 39, the Examiner stated that Beard ‘296 discloses a method of modulating joint stiffness or damping of an ankle joint of an orthosis at least three times during each walking cycle wherein the method includes adjusting the stiffness of the joint during controlled plantar flexion and minimizing impedance during late stance.

Beard ‘296 discloses a biofeedback activated orthosis configured for foot-drop rehabilitation. The orthosis includes foot brace 2 secured to the foot of the user that includes lifting cable 3 for lifting foot 54 throughout a gait cycle. (See Col. 4, lines 40-43). Beard ‘296 also discloses a device 8 for sending a signal to a controller to represent an angular relationship between the lower leg and the thigh (See Col. 4, lines 60 through Col. 5, line 3). If both muscle

activity parameters and the angular relationship between the lower leg and the thigh are met, then a processing signal is sent to activate gear motor 29 to timely apply tension to the cable and to pull upwardly foot brace 2. (See Col. 5, lines 48-58).

Applicants claim a variable-impedance active ankle foot orthosis device. In one embodiment, the device includes an actuator and a spring. The spring is linked to the actuator. The actuator modulates or selectively varies an impedance of the ankle joint by controlling the spring. This modulation is not disclosed or suggested by Beard et al.

One embodiment of Applicants' claimed invention is described at pages 4-5 and Fig. 1, which discloses that the actuator 12 includes a brushless DC motor operatively connected in series with a spring. The actuator provides force control by controlling the extent that the spring is compressed. In another embodiment, the orthosis device further includes sensors 14 and 16, or more particularly, a ground reaction sensor and an ankle angle sensor to provide feedback to the actuator, which then modulates an impedance of an ankle joint by controlling the spring.

The Beard '296 device is not a variable-impedance active ankle orthosis. The Examiner's cited passages do not disclose or suggest any variable-impedance active ankle orthosis. The Beard '296 device simply does not modulate the impedance of the ankle joint in an updating manner from step-to-step of a walk cycle.

The Examiner also stated, that with respect to Claim 37, that "there is inherently a joint formed between the leg portion 4 and foot portion 2" of the device disclosed by Beard '296. The Examiner further stated that, "alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology." Regarding Claim 39, the Examiner stated that "[i]t is noted that the joint between the leg portion and the foot portion inherently exists and is inherently modulated throughout the gait." Further, the Examiner stated that "[i]t is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore, anticipated the claims."

The Examiner's assertion that the variable impedance of Applicants' claimed invention is inherent in the "joint" between the leg portion 4 and the foot portion 2 is erroneous since there is no joint between the leg portion 4 and the foot portion 2. Moreover, Applicants' system selectively varies, or selectively changes, the impedance of an ankle joint from step-to-step

during a walk cycle, while Beard '296 simply uses feedback to activate the motor and to pull the cable 3, and to pull upwardly the foot brace 2. The amount of impedance in Beard '296 is the same from step-to-step.

In addition, if it is the Examiner's assertion that the impedance of the ankle joint of the individual is what is being modulated, this too is also erroneous. Applicants contend that the impedance of the ankle joint between the leg and the foot (when the individual is wearing the Beard '296 device) is the same throughout the walking cycle and is not modified or varied. The cable 3 of the Beard '296 device simply lifts the foot 54 throughout a walking or gait cycle.

Moreover, simply because the cable 3 of Beard '296 lifts the foot 54 throughout a gait cycle does not mean that the impedance of the ankle joint is varied or modulated, let alone actively and throughout the walking cycle. Applicants' varying of impedance from step-to-step of a walking cycle is especially advantageous since Applicants' device can vary impedance quickly in response to gait speed of the individual. (See Applicants' specification at page 8, lines 19-28). Applicants respectfully submit that the individual's ankle joint wearing the Beard '296 device has the same impedance regardless of whether the foot is being lifted by the cable 3 or not.

The Examiner is mistaken by equating merely lifting the foot with Applicants' device for modulating or selectively changing an impedance of the ankle joint throughout a walking cycle for treating an ankle foot gait pathology. The Beard '296 device does nothing to change the impedance of the ankle joint, and simply provides a tensile force to the foot about the foot portion.

Finally, the assertion that the knee joint is considered to anticipate the claims is also erroneous, since, again, the impedance of the knee joint is unchanged by the Beard '296 device. At most, Beard '296 discloses that a backlash inhibiting device 67 prevents backlash at cable 3 by maintaining a minimum amount of tension in cable 3 at all times. Beard '296 does not modulate any impedance of the ankle joint, nor is an ankle joint selectively controlled as presently claimed in independent Claims 37 and 39.

Reconsideration and withdrawal of the rejection of independent Claims 37 and 39 are respectfully requested.

Rejection of Claims 24 and 33-36 Under 35 U.S.C. § 102(b) in View of Stein '332

Claims 24 and 33-36 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 5,643,332, issued to Stein (hereinafter Stein '332). In particular, the Examiner stated that Stein '332 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during controlled plantar flexion and minimizes forefoot collision. Regarding modulation during the swing phase, the Examiner made reference to Col. 6, lines 34-55.

Stein '332 teaches an electrical stimulation device which causes a depolarization of the underlying membrane, and which causes propagation of an impulse along the nerve and contraction of the muscle. Stein '332 does not disclose or suggest modulating joint stiffness or damping in an updating manner from step-to-step of a walk cycle, as claimed by Applicants. Col. 6, lines 34-55 of Stein '332 do not, as asserted by the Examiner, teach modulation during a swing phase, but rather an on/off electrical stimulation which, as the Examiner had previously stated in an Interview Summary dated November 1, 2007, is "deficient in disclosing modulation of stiffness and damping in the ankle joint," because Stein '332 "again discloses a system in which the joint is either locked at an upward position to avoid the toe strike or fully released to allow free motion during heel strike and walkover."

Therefore, independent Claim 24, and Claims 33-36, which depend from independent Claim 24, are novel in view of Stein '332 under 35 U.S.C. § 102(b). Reconsideration is respectfully requested.

Rejection of Claims 1-9, 11-23, 25-29, 32 and 37-40 Under 35 U.S.C. § 102(b) in View of Johnson '693

Claims 1-9, 11-23, 25-29, 32 and 37-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,662,693, issued to Johnson, et al. (hereinafter Johnson '693). The Examiner stated that particular emphasis is placed on the abstract, Figs. 1, 3C, 5 and 9; and Col. 8, lines 4-14; Col. 9, lines 3-27; and Col. 10, lines 55-65.

Johnson '693 discloses an exo-skeleton that is capable of providing a normal person with additional strength and support, thereby creating a state of super mobility. (See Col. 6, lines 53-59). The exo-skeleton includes an apparatus that includes braces that reinforce four segments of

the patient's legs. In one embodiment, the person may have a mobility impairment below the ankle, the knee or the upper thigh. (See Col. 6, lines 60-67). These braces cover the entire leg and is not an active ankle foot orthosis.

The braces included pneumatic actuators to allow for various force states of the brace. The actuators provide contractile forces about a joint 113 creating and sustaining torque required for mobility enhancement or stability. (See Col. 7, lines 26-35).

Col. 8, lines 5-34 disclose that, in a human ankle joint, contractile forces that are associated with the ankle joint include a large force in the foot plantation movement and a relatively smaller toe lift force. Johnson discloses that a spring can be provided to substitute for an opposing muscle in a lopsided torque requirement to balance forces between the foot plantation movement and the toe lift.

Col. 8, lines 15-25 of Johnson discloses that integration of goniometric inputs from the fingers, control actuators, and sensors make the active orthosis function as a functioning mobility assist device. However, Johnson does not disclose or suggest a device for modulating an impedance of an ankle joint in an updating manner from step-to-step of a walk cycle. In contrast, Johnson discloses an exo-skeleton that provides the forces necessary for the walking cycle. (See Col. 2, lines 5-28).

Johnson does not disclose or suggest modulating an impedance of the ankle joint throughout a walking cycle, but instead discloses providing contractile forces to joints associated with the exo-skeleton to provide mobility. Johnson discloses that the patient using the brace can set the amount of stiffness of the legs for any force or load. This provides that the legs wearing the brace can be self-stable. This is not the same as modulating an impedance of the ankle joint in an updating manner from step-to-step of a walk cycle.

Claim 1 is novel under 35 U.S.C. § 102(b) and, therefore, reconsideration and withdrawal of this rejection are respectfully requested. Claims 2-9, 11 and 26-29 depend from Claim 1, and are patentable for at least the reasons discussed above for Claim 1. Independent Claims 12 and 19 are also patentable for at least the same reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30 and 32 depend from Claim 19 and are patentable for at least the same

reasons discussed above for Claim 19. Claims 37-40 are all independent Claims, and are patentable for the same reasons discussed with respect to independent Claim 1 above.

Rejection of Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 Under 35 U.S.C. § 102(e) in View of Horst '882

Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,966,882 to Horst et al. (hereinafter Horst '882). The Examiner stated that "particular emphasis is given to the abstract, Figs. 1 and 4-6 and related paragraphs, particularly as pertains to assist, monitor, and rehabilitate modes 508-512 (Fig. 5) to address the adaptive nature of the modulation. Further, the Examiner stated that Horst '882 discloses computer-controlled actuation in Col. 3, lines 41-58 and updating at least three times per walk cycle in Col. 5, lines 63 through Col. 6, line 28.

Horst discloses a brace device which is attached at the knee. The structural frame of the device includes pair of hinges 18 at the medial and lateral sides of the brace. (See Column 5, lines 1-15). The brace device also includes an actuator 12 that is coupled to the brace to provide the force needed to assist or resist the leg muscle during rotation. The actuator 12 includes a rotary motor. The rotary motor has a center of rotation which is located close to a center of rotation of the knee joint (See Col. 7, lines 28-44).

Horst '882 does not disclose or suggest a device for modulating an impedance of an ankle joint in an updating manner from step-to-step of a walk cycle. In contrast, Horst '882 discloses a brace device for rotating a knee joint to assist or resist (for an exercise) a primary movement direction of a leg muscle. (See Col. 7, lines 18-26). At most, Horst '882 discloses that the device may be used to assist with rotation of an ankle joint at Col. 7, line 25. However, Horst '882 does not disclose or suggest modulating an impedance at the ankle in an updating manner from step-to-step of a walk cycle for treating an ankle for gait pathology. In contrast, Horst '882 discloses providing a rotating force to a portion of a brace located at the knee joint using a number of sensors. This is not modulating and impedance of the ankle joint in an updating manner from step-to-step of a walk cycle, and Claim 1 is novel under 35 U.S.C. § 102(e).

Reconsideration and withdrawal of this rejection of Claim 1 are respectfully requested. Claims 2-4, 6-8, 11 and 26-28 depend from Claim 1 and are patentable for at least the reasons

discussed above for Claim 1. Independent Claims 12, 19 and 25 are also patentable for at least the reasons discussed above for Claim 1. Claims 13-18 depend from Claim 12 and are patentable for at least the same reasons discussed above for Claim 12. Claims 20-23, 29-30 and 32 depend from Claim 19 and are patentable for at least the same reasons discussed above for Claim 19. Claims 37-40 are all independent claims and are patentable for at least the reasons discussed with respect to Claims 1, 12, 19 and 25.

Rejection of Claim 41 Under 35 U.S.C. § 102(e) in View of Goffer '021

Claim 41 stands rejected under 35 U.S.C. § 102(e) as being clearly anticipated by U.S. Publication No. 2003/0093021, to Goffer (hereinafter Goffer '021). In particular, the Examiner referred to selected paragraphs of Goffer '021 as describing a method of treating an ankle foot gait pathology use in functional electrical stimulation in conjunction with a traditional orthosis or brace. Further, the Examiner restated that Goffer '021 discloses computer-controlled actuation.

As with the references previously cited by the Examiner, Goffer '021 does not disclose method of treating an ankle foot gait pathology employing electrical pulses to elicit muscle contractions to actively modulate, by computer-controlled actuation, ankle stiffness or damping, or both, wherein modulation of joint impedance is adaptive in nature, whereby information from each gait cycle causes further modulations that vary in joint impedance from one gait cycle to the next, wherein joint stiffness or damping or both are further modulated by controlling a spring associated with an orthosis as claimed by Applicant. Therefore, Goffer '021 does not anticipate the subject matter of Applicant's independent Claim 41.

Rejection of Claims Under 35 U.S.C. § 103(a) in View of Beard '296

Claims 1, 2, 4, 6-8, 10, 11, 19, 20, 22, 29 and 30 stated rejected under 35 U.S.C. § 103(a) in view of Beard '296. In particular, the Examiner stated that "Beard '296 is considered to disclose the invention substantially as claimed including adaptive and updating control of joint stiffness or damping, but does not expressly disclose that the updating occurs at least three times during each walk cycle." The Examiner stated that it "would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art."

Claims 1 and 19 of this rejection are independent, and the remaining claims are dependent from either independent Claims 1 or 19. As discussed above with respect to Claims 37 and 39, Beard '296 does not disclose modulation of joint stiffness or damping of an ankle joint in an updating manner of a variable-impedance active ankle foot orthosis, as claimed by Applicants in independent Claims 1 and 19.

There is no disclosure or suggestion, nor would one of ordinary skill in the art be motivated to modify the teachings of Beard '296 to obtain Applicants' claimed variable-impedance active ankle foot orthosis and method, as claimed in independent Claims 1 and 19, respectively. As a result, Applicants' claimed subject matter of independent Claims 1 and 19, and claims dependent therefrom, meet the requirements of 35 U.S.C. 103(a) in view of Beard '296.

Rejection of Claim 9 Under 35 U.S.C. 103(a) in View of Beard '296, Swain '757 or Naft '503

Claim 9 stands rejected as being unpatentable under 35 U.S.C. 103(a) in view of Beard '296, in view of U.S. 6,507,757, issued to Swain, et al. (hereinafter Swain '757) or in view of U.S. 6,517,503 to Naft, et al. (hereinafter Naft '503). In particular, the Examiner stated that Beard '296 discloses the invention substantially as claimed but does expressly disclose a foot switch. Accordingly, the Examiner stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard '296 with the foot switch of either Swain '757 or Naft '503 to provide the Beard '296 system with the same advantage of improving patient gait and treating drop foot ("motivation to combine provided by the abstracts of Swain et al. and Naft et al.").

Claim 9 depends from independent Claim 1 and, therefore, contrary to the Examiner's statement, Beard '296 does not disclose the invention substantially as claimed but for the presence of a foot switch. As stated above, Beard '296 does not disclose or suggest, nor would one of ordinary skill in the art be motivated in view of Beard '296, to modify the teachings in Beard '296 to include modulation of joint stiffness or damping of an ankle joint in an updating manner, as does Applicants' claimed and variable-impedance active foot orthosis. Neither Swain '757 nor Naft '503 remedy the deficiencies of Beard '296. Therefore, dependent Claim 9 meets

the requirements of 35 U.S.C. § 103(a), in view of Beard '296, Swain '757 and Naft '503, taken separately or in any combination.

Rejection of Claims 24 and 33-36 Under 35 U.S.C. 103(a) in View of Swain '757

Claims 24 and 33-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Swain '757. In particular, the Examiner stated that Swain '757 clearly discloses the invention as claimed with the exception of updating at least three times during each walk cycle. The Examiner stated that it "would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein repetition of steps in a known process involves only routine skill in the art."

As discussed above, Swain '757 lacks disclosure of modulating of mechanical properties of stiffness and damping in the ankle joint in an updating manner, as stated by the Examiner in an Interview Summary prepared by the Examiner mailed from the United States Patent and Trademark Office on November 1, 2007. Therefore, Swain '757 fails, as does Beard '296 and all other references cited by the Examiner in other rejections of Claim 24 and Claims 33-36, which depend from Claim 24, to disclose or suggest, or provide motivation to one of ordinary skill in the art, to obtain Applicants' claimed method of treating an ankle foot gait pathology.

Rejection of Claim 31 Under 35 U.S.C. § 103(a) as Being Unpatentable Over Goffer '021

Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Goffer '021. In particular, the Examiner stated that Goffer '021 discloses the invention substantially as claimed, but does not expressly disclose that the updating occurs at at least three times per walk cycle, and that it would have been obvious to one of ordinary skill in the art at the time of the invention to update a third time during the cycle as it merely constitutes a repetition of an updating step, wherein a repetition of steps in a known process involves only routine skill in the art.

Goffer '021 does not disclose or suggest, nor would one of ordinary skill in the art be motivated to modify the teachings of Goffer '021 to obtain a method for treating an ankle foot gait pathology using functional electrical stimulation by applying computer-controlled electrical

pulses to elicit muscle contractions to actively modulate ankle stiffness or damping, or both in an updating manner from step-to-step of walking cycle, wherein the joint stiffness or damping are modulated by controlling the spring associated with orthosis, as claimed by Applicant.

Therefore, Applicants' method, as claimed in independent Claim 31, meets the requirements of 35 U.S.C. § 103(a) in view of Goffer '021.

Recitation of Other Art Not of Record

The Examiner recited several references not previously of record. The references were not made part of any formal rejection. Applicants' variable impedance active ankle foot orthosis meets the requirements of 35 U.S.C. § 102 in view of the cited references. Further, one of ordinary skill in the art would not be motivated in view of the teachings of references cited by the Examiner, including U.S. Publication 2002/0052663, to Herr *et al.* In particular, one of ordinary skill in the art would not be motivated to modify the teachings of Herr *et al.* in Publication 2002/0052663, which are directed to automatic adjustment of stance and swing phase knee resistance to thereby obtain a device configured to modulate by computer control actuation of impedance, including joint stiffness and damping of the ankle joint to treat ankle foot gait pathology, as claimed by Applicants. Further, none of the other references cited by the Examiner remedy the deficiencies of Herr *et al.*, U.S. Publication 2002/0052663.

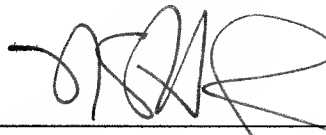
SUMMARY AND CONCLUSIONS

The claims have been amended to more particularly point out and distinctly claim what Applicants consider to be their invention. Further, Applicants have amended the claims to specify that "joint stiffness or damping of an ankle joint" are embodiments of impedance, which has now been positively recited in the claims, as requested by the Examiner. Applicants' claimed invention meet the requirements of 35 U.S.C. §102 and 103 in view of all of the references cited, taken separately or in any combination. Therefore, Applicants respectfully request reconsideration and withdrawal of all outstanding rejections and to pass the application to allowance.

If the Examiner believes that a telephone conference would expedite prosecution of this application, she is invited to call Applicant's undersigned attorney.

Respectfully submitted,

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